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PATENT Attorney Docket No. 040285PCTUS

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of LeDuc, et al. Art Unit: 1645

Serial No.: 10/553,249

THREE-DIMENSIONAL, FLEXIBLE CELL GROWTH SUBSTRATE AND RELATED

**METHODS** 

## INFORMATION DISCLOSURE STATEMENT

November 9, 2006 Pittsburgh, Pennsylvania 15222

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants, in accordance with their duty of disclosure pursuant to 37 C.F.R. § 1.56, hereby advise the United States Patent and Trademark Office of the references listed on the accompanying form PTO/SB/08A (substitute for 1449A/PTO) Information Disclosure Statement by Applicant. Copies of each non-U.S. Patent reference cited therein are herewith enclosed. Applicants note that although the cited references may be relevant to the examination of the above-referenced application "under 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement "shall not

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be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b)."

Applicants further note that the filing of this *Information Disclosure Statement* by Applicant is not an admission that the references cited herein constitute prior art under 35 U.S.C. §§ 102-103 with respect to the captioned application.

Pursuant to 37 C.F.R. § 1.97(b) (3), Applicants submit that no fee is necessary for consideration of this *Information Disclosure Statement* by Applicant. Nevertheless, the Commissioner is hereby authorized to charge any additionally required fees deemed necessary for consideration of this *Information Disclosure Statement* by Applicant to Account No. 11-1110.

Respectfully submitted,

C. Allen Black, Ur.

Registration No. 53,835 Attorney for Applicants

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	Complete if Known		
Substitute for form 1449A/PTO	Application Number	10/553,249	
	Filing Date	October 17, 2005	
INFORMATION DISCLOSURE	First Named Inventor	LeDuc, et al.	
STATEMENT BY APPLICANT	Art Unit	1645	
(	Examiner Name	Not Yet Assigned	
(use as many sheets as necessary)			
Sheet 1 of 5	Attorney Docket Number	040285PCTUS	

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		US-4,789,601	12/06/1988	Banes			
		US-6,048,723	04/11/2000	Banes			
		US-6,037,141	03/14/2000	Banes			
		US-6,645,759 B2	11/11/2003	Banes			
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	FOREIGN PATENT DOCUMENTS						
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	1	WO 02/35990 A2	May 10, 2002	Prodesco, Inc.		T	
		WO 91/19783	Dec. 26,1991	E.I. DuPont De Nemours and Company			
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Enter Office that issued the document, by the two-letter code (WIPO) Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Complete if Known Substitute for form 1449A/ **Application Number** 10/553,249 Filing Date October 17, 2005 INFORMATION DISCLOSURE **First Named Inventor** LeDuc, et al. STATEMENT BY APPLICANT Art Unit 1645 **Examiner Name** Not Yet Assigned (use as many sheets as necessary) Attorney Docket Number 040285PCTUS Sheet 2

	NON PATENT LITERATURE DOCUMENTS					
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²			
		BOITANO, S., et al., A Role for Ca2+ -Conducting Ion Channels in Mechanically-induced Signal Transduction of Airway Epithelial Cells, <u>Journal of Cell Science</u> 107, pp. 3037-3044 (1994).				
		CAMARGO, M., et al., Renal Hydrolysis of Absorbed Protein: Influence of Load and Lysosomal pH, Am J Physiol 247, pp. F656-64, (1984).				
		CHAOHONG L., et al., Cyclic Strain Stress-induced Mitogen-activated Protein Kinase (MAPK) Phosphatase 1 Expression in Vascular Smooth Muscle Cells is Regulated by Ras/Rac-MAPK Pathways, The Journal of Biological Chemistry Vol. 274, No. 36, pp. 25273-25280, (1999).				
		CHESS, et al., Mechanical Strain-Induced Proliferation and Signaling in Pulmonary Epithelial H441 cells, Am J Physiol Lung Cell Mol Physiol 279, pp. L43-L51, (2000).				
		DEKKER, R., et al., Prolonged Fluid Shear Stress Induces a Distinct Set of Endothelial Cell Genes, Most Specifically Lung Krüppel-like Factor (KLF2), Blood, 100, No. 5, pp. 1689-1698, (2002).				
		ENGSTROM K, et al., Combined Use of Micropipette Aspiration and Perifusion for Studying Red Blood Cell Volume Regulation, Cytometry 27, pp.345-352 (1997).				
		FERRER I.,et al., Phosphorylation-Dependent Mitogen-Activated Protein Kinase (MAPK/ERK), Stress-Activated Protein Kinase/c-Jun N-Terminal Kinase (SAPK/JNK), and p38 Kinase Expression in Parkinson's Disease and Dementia with Lewy Bodies, J Neural Transm_108, pp. 1383-1396, (2001).				
		GARCIA-CARDENA G., et al., Mechanosensitive Endothelial Gene Expression Profiles: Scripts for the Role of Hemodynamics in Atherogenesis?, Ann N Y Acad Sci 947: 1-6, (2001).				

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HAMMERSCHMIDT, S., et al., Apoptosis and Necrosis Induced by Cyclic Mechanical Stretching in Alveolar Type II Cells, Am J Respir Cell Mol Bio 30, pp. 396-402, (2004).	
HUSSE, B., et al., Cyclical Mechanical Sstretch-induced Apoptosis in Myocytes from Young Rats but Necrosis in Myocytes from Old Rats, Am J Physiol Heart Circ Physiol 285, pp. 1521-1527, (2003).	· · · · · ·
JANSSON, K.,et al., A Biodegradable Bovine Collagen Membrane as a Dermal Template for Human In Vivo Wound Healing, Scand J Plast Reconstr Surg Hand Surg 35, pp. 369-75, (2001).	
KANO, Y., et al., Lateral Zone of Cell-Cell Adhesion as the Major Fluid Shear Stress-Related Signal Transduction Site, Circulation Research, Journal of the American Heart Association 86; pp. 425-433, (2000).	
LEDUC P., et al., <i>Dynamics of Individual Flexible Polymers In a Shear Flow</i> , Nature 399, pp. 564-566, (1999).	
LEDUC P., et al., Use of Micropatterned Adhesive Surfaces for Control of Cell Behavior, Methods in Cell Biology 69, pp. 395-401 (2002).	
LEVENBERG, S., et al., Differentiation of Human Embryonic Stem Cells onThree- Dimensional Polymer Scaffolds, PNAS 100, No. 22, pp. 12741-12746, (2003).	
LIU, S., et al., A Possible Role of Initial Cell Death Due to Mechanical Stretch in the Regulation of Subsequent Cell Proliferation in Experimental Vein Grafts, Biomech Model Mechanobiol 1, pp.17-27, (2002).	
MALEK, A., et al., Mechanism of Endothelial Cell Shape Change and Cytoskeletal Remodeling in Response to Fluid Shear Stress, Journal of Cell Science, 109, pp. 713-726, (1996).	
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INFORMATION DISCLOSURE			SURE	First Named Inventor	LeDuc, et al.	
STATEMENT BY APPLICANT		Art Unit	1645			
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Sheet	4	of	5	Attorney Docket Number	040285PCTUS	

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	MATSUDA, et al., Proliferation and Differentiation of Human Osteoblastic Cells Associated with Differential Activation of MAP Kinases in Response to Epidermal Growth Factor, Hypoxia, and Mechanical Stress in Vitro, Biochemical and Biophysical Research Communications 249, pp. 350-354, (1998).	
	MEYER, et al., Mechanical Control of Cyclic AMP Signalling and Gene Transcription Through Integrins, Nature Cell Biology 2, pp. 666-668, (2000).	
	MORIMOTO, N.,et al., Excess Plasma Membrane and Effects of Ionic Amphipaths on Mechanics of Outer Hair Cell Lateral Wall, Am J Physiol Cell Physiol 282 ,pp. C1076-1086, (2002).	
	RESNICK N., Endothelial Gene Regulation by Laminar Shear Stress, Adv Exp Med Biol 430, pp.155-164, (1997).	
	SCHNITTLER H., et al., Role of Actin Filaments in Endothelial Cell Adhesion and Membrane Stability Under Fluid Shear Stress, Pflugers Arch 442, pp.675-687, (2001).	
	SHRODE, L., et al., Cytosolic Alkalinization Increases Stress-Activated Protein Kinase/c-Jun NH2 Terminal Kinase (SAPK/JNK) Activity and p38 Mitogen-activated Protein Kinase Activity by a Calcium-independent Mechanism, The Journal of Biological Chemistry Vol. 272, No. 21, pp. 13653-13659, (1997).	
	SUMPIO, B., et al., Mechanical Stress Stimulates Aortic Endothelial Cells to Proliferate, J. Vasc Surg 6, pp. 252-6 (1987).	
	TOPPER, J., et al., Blood Flow and Vascular Gene Expression: Fluid Shear Stress as a Modulator of Endothelial Phenotype, Mol Med Today 5, pp. 40-46 (1999).	1
	TRUSKEY, G., et al., The Effect of Fluid Shear Stress Upon Cell Adhesion to Fibronectin- treated Surfaces J Biomed Mater Res 24, pp.1333-1353 (1990).	

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VAN KOOTEN, T., et al. Fluid Shear Induced Endothelial Cell Detachment from Glass- Influence of Adhesion Time and Shear Stress, Med Eng Phys 16, pp. 506-512 (1994).		
WANG, J., et al., Specificity of Endothelial Cell Reorientation in Response to Cyclic Mechanical Stretching, J Biomech 34, pp.1563-1572 (2001).		
WANG, N., et al., Mechanotransduction Across the Cell Surface and Through the Cytoskeleton, Science 260, pp. 1124-1127 (1993).		
WANG, Y., et al., A Tough Biodegradable Elastomer, Nature Biotechnology, 20, pp. 602-606 (2002).		
WANG, J., et al., Development of Biodegradable Polyesterurethane Membranes With Different Surface Morphologies for the Culture of Osteoblasts, pub. John Wiley & Sons, Inc. pp. 761-770 (2000).		
WEYTS, F., et al., Mechanical Control of Human Osteoblast Apoptosis and Proliferation in Relation to Differentiation, Calcif Tissue Int 72, pp.505-12 (2002).		

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